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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,907	ZHONG ET AL.	
	Examiner	Art Unit	
	Ruth S Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) 39-68 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/4/03, 2/12/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-38, drawn to a medical device, classified in class 600, subclass 420.

II. Claims 39-48, drawn to the use of a medical device, classified in class 600, subclass 420.

III. Claims 49-58, drawn to the use of a hydrogel polymer, classified in class 424, subclass 9.3.

IV. Claims 59-68, drawn to a hydrogel polymer, classified in class 424, subclass 9.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a method that does not involve imaging.

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method can be used on a device that does not include a substrate.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a non-medical environment.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a non-medical environment.

Because these inventions are distinct for the reasons given above and the search required for Groups I-IV is not the same, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Bonham on January 25, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-68 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5,35 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox. Cox discloses an insertable medical device such as a catheter or guidewire comprising

a substrate such as the guidewire and a hydrogel polymer coating disposed on the substrate. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The polymer will inherently possess the properties as set forth in claims 2-5.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bergheim et al. Bergheim et al disclose an implantable medical device comprising a substrate such as the implant 31and a hydrogel coating disposed on the substrate. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 2-4.

Claims 1-5,9,30,35 are rejected under 35 U.S.C. 102(b) as being anticipated by DiCosmo et al. DiCosmo et al disclose an insertable medical device comprising a substrate such as a catheter and a hydrogel coating disposed on the substrate. The hydrogel polymer can be cross-linked. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 2-5.

Claims 1-7,9,30,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne. Whitbourne discloses a medical device such as a catheter comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 2-7.

Claims 1-8,30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbluth et al. Rosenbluth et al disclose an insertable medical device comprising a substrate such as the pad 12 and a hydrogel polymer coating disposed on the substrate. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess

the properties as set forth in claims 2-8. The coating can include the ingredients as set forth in claims 4-8, 30-32. The hydrogel can be as disclosed in US Patent No. 4,593,053 as disclosed in column 5. The materials disclosed in the cited patent are as set forth in the claims.

Claims 1-5,9-11,13-22,28-31,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 2-5. The hydrogel composition can be cross-linked and can include paramagnetic particles/ions as set forth in the claims. With respect to claims 16, 18, Weissleder et al disclose that the paramagnetic materials may be covalently bonded to the hydrogel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Michaels. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. Michaels discloses the use of a hydrogel coating that contains glycerin so as to prevent cracking during the drying process of the coating. It would have been obvious to one skilled in the art to have modified Weissleder et al such that glycerin is applied to the hydrogel to prevent cracking when the coating is applied to the medical device.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Klaveness et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 2-5. The hydrogel composition can be cross-linked and can include paramagnetic particles/ions as set forth in the claims. Weissleder et al fails to specifically disclose the use of starch-coated iron oxide particles. Klaveness et al disclose MRI detectable materials comprising starch-coated iron oxide particles. It would have been obvious to one skilled in the art to have modified Weissleder et al such that the paramagnetic particles used are starch-coated iron oxide particles. Such a modification involves the substitution of one known type of paramagnetic particles detectable by MRI for another.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Peng et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under

MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 2-5. The hydrogel composition can be cross-linked and can include paramagnetic particles/ions as set forth in the claims. Weissleder et al fails to disclose the use of aminopolycarboxylic acid. Peng et al disclose in paragraph 50 that aminopolycarboxylic acid is a know chelating agent for use with paramagnetic particles in MRI. It would have been obvious to one skilled in the art to have modified Weissleder et al such that it includes aminopolycarboxylic acid as the chelating agent for use with paramagnetic particles. Such a modification merely involves the substitution of one well known type of chelating agent for another.

Claims 24-27,32,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Cleary et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. Weissleder et al fails to disclose the use of acrylic acid. Cleary et al disclose hydrogel compositions that include substituted or unsubstituted acrylic acid, polyacrylic acid, and a copolymer of acrylic acid and acrylamide. It would have been obvious to one skilled in the art to have modified Weissleder et al such that the hydrogel composition is as taught by Cleary et al. Such a modification merely involves the substitution of one known type of hydrogel composition for another.

Claims 34,36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al. Weissleder et al disclose a medical device comprising a substrate such as a interventional medical device and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The coating should provide a lubricious layer by itself once it contacts bodily fluids, however it would have been obvious to one skilled in the art to have provided an additional layer to ensure that the coating exhibits lubricious properties upon entry into the patient to prevent harm from coming to the patient as

such is a well known expedient in the art. With respect to claims 36-38, it would have been obvious to one skilled in the art to have applied the coating to any type of device placed in the body for which one needs to monitor its location.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Beall discloses the use of cross-linked hydrogel in an MRI environment. The hydrogel has shorter T_1 and T_2 values than surrounding tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (571) 272-4745. The examiner can normally be reached on M-F 7:30 AM- 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth S Smith
Primary Examiner
Art Unit 3737

RSS